

Implementing Shared Decision Making
(SDM)
For Individualized CV Prevention
(SDM4IP)

NCT04450914

April 17, 2024

Implementing Shared Decision Making (SDM) for Individualized CV
Prevention (SDM4IP)

Jennifer Ridgeway, co -Principal Investigator, Mayo Clinic
200 First Street SW, Rochester, MN 55905
507-284-4993
Jennifer.Ridgeway@mayo.edu

Victor Montori, co-Principal Investigator, Mayo Clinic
507-538-0587
Victor.Montori@mayo.edu

Date of version: April 17, 2024
Version number: 6.0

Funding Source: NHLBI 1R01 HL 151662-01

Table of Contents

1.0 Specific Aims	4
2.0 Background/Significance	4
3.0 Preliminary Work	6
3.1 Development of SDM tools	6
4.0 Research Design & Methods	7
4.1 Overview.....	7
4.2 Schema.....	7
4.3 Phases of study.....	8
4.4 Study Setting and Participation	9
4.4.1 Health Systems	9
4.4.1.1 Recruitment of Health Systems	10
4.4.2 Sites for Health Systems.....	10
4.4.2.1 Recruitment of Sites.....	10
4.4.3 Clinicians	10
4.4.3.1 Clinician Recruitment.....	10
4.4.4 Study Subjects (Patients)	10
4.4.4.1 Study Subject Recruitment	11
4.5 Description of the Intervention	11
4.6 Data Collection	16
4.7 Analysis Plan	20
4.7.1 Data Analysis – Aim 1	20
4.7.2 Data Analysis – Aim 2	21
4.7.3 Sample Size Estimation.....	22
4.7.4 Site Allocation.....	23
5.0 Potential Limitation	23
6.0 Human Subjects.....	23
6.1 Population	24

6.2	Potential Risks	24
6.3	Protection and Confidentiality	25
	6.3.1 Subject privacy	25
	6.3.2 Data management:	25
	6.3.3 Video and audio-recordings.....	25
	6.3.4 Data and Safety Monitoring Plan.....	26

1.0 Specific Aims

Our broad goal is to promote patient-centered care that effectively reduces the substantial burden of cardiovascular (CV) disease among Americans. We hypothesize that efforts to assess local needs of health care systems and clinical team members and use them to develop tailored implementation approaches will foster greater adoption of shared decision making (SDM) in practice. We further hypothesize that individual preventive care plans will be congruent with estimated risk when clinicians adopt the CV PREVENTION CHOICE tool for SDM.

By the project's end, we expect to have (a) identified the most effective implementation strategies to embed SDM in routine practice and (b) estimated the effectiveness of SDM to achieve feasible and risk-concordant CV prevention. There are two specific aims:

Specific Aim 1: To determine the effectiveness of implementation strategies on CV PREVENTION CHOICE uptake and routine use by employing a multilevel evaluation of: (a) the practice context and methods to engage users in identifying and tailoring implementation strategies; (b) the implementation outcomes (e.g., reach, adoption) associated with tailored implementation strategies; and (c) the work clinicians do to normalize use of CV PREVENTION CHOICE in routine practice.

Specific Aim 2: To estimate the extent to which CV PREVENTION CHOICE, as implemented in practice, results in individual CV prevention plans that are evidence-based, congruent with each person's estimated CV risk, and feasible within each patient's personal and psychosocial context.

2.0 Background/Significance

CV disease is the #1 cause of premature mortality and substantial morbidity in the U.S. More than 0.7 million Americans die each year (202 per 100,000 Americans) from CV causes,¹ accounting for 1 of every 3 deaths in the U.S.^{2,3} CV disease is a highly significant and costly public health problem both in terms of human lives and in healthcare use. The prevention of CV events and of the subsequent disability, suffering and death is therefore of high priority. While public health interventions (e.g., smoking bans and restriction of tobacco sales to minors) can reduce the burden of CV disease in the population, clinical prevention can target high-risk individuals. Clinical primary CV prevention is enabled by progress in the ability to estimate an individual's CV risk based on epidemiological factors and the estimation, in large-scale randomized trials, of the effect of clinical interventions in reducing this risk.⁴ These developments, synthesized into clinical practice guidelines, should translate into a substantial reduction in CV burden by promoting public health interventions aimed at the largest lower risk population, while targeting individuals at the highest risk and implementing in their care effective interventions to reduce this risk. Yet, a persistent finding in real-world evidence

indicates a critical practice gap: most clinical interventions are implemented in people at relatively lower CV risk, and few among people at the highest risk.^{5,6} This so-called risk-treatment paradox has been observed repeatedly across a range of CV-risk reducing interventions such as statins and aspirin. Recent studies, completed by our team using the OptumLabs Data Warehouse, a de-identified dataset of geographically, demographically, and socioeconomically diverse group of commercially-insured and Medicare Advantage beneficiaries, demonstrate that treatments to reduce CV risk in patients with type 2 diabetes are less likely to be prescribed to the patients at the highest CV risk who are most likely to benefit from them.⁷ Compared to lower risk patients, SGLT2 inhibitors were less likely to be prescribed in patients with heart failure or chronic kidney disease (CKD) and GLP1 receptor agonists were less likely to be prescribed in patients with ASCVD or CKD despite cardiovascular outcomes trial data showing CV risk reduction with these agents in these high risk groups. These analyses also revealed that black patients (vs. white),⁷ women (vs. men), and those covered by Medicare Advantage (vs. commercial insurance with identical formulary coverage)⁷ were less likely to receive these agents. Thus, we have new evidence that confirms the persistence of the risk-treatment paradox and the introduction of additional disparities based on race, gender, and insurance coverage.

Patients and clinicians working together can consider the threat posed by CV disease and craft a sensible and feasible plan of care to address this threat. This so-called shared decision making (SDM) can mitigate the risk-treatment paradox that is not related to inequitable access to clinical care by reducing risk blindness and lack of fit of the preventive regimen.⁸ The appropriate treatment regimen should be commensurate to each person's level of CV risk and should make intellectual, practical and emotional sense for that particular patient. Patients who appear to have implemented preventive therapies are often unaware of their own risk, vary in their preferences for intensity and modality (pharmacological vs. lifestyle) of prevention, and usually are unable to connect the medications they are taking with their preventive goal. SDM – facilitated by risk estimation and risk communication tools used during the clinical encounter – has proven effective in correcting the risk treatment paradox and the distortions of decision making at its root. Despite their efficacy, broad uptake of SDM has faltered in practice because of patient and clinician attitudes or preferences, time constraints on clinic visits, and organizational or public policies that favor traditional disease management (e.g., the pursuit of population targets) approaches. Careful integration of an SDM tool into the electronic workflow may reduce barriers to use, but EHR integration alone is not sufficient for routine use due to multilevel personal, organizational and systemic barriers. The identification and evaluation of implementation strategies addressing broad challenges to implementation is required.

The purpose of this study is to identify implementation approaches that foster routine, high-quality SDM about CV prevention in the care of at-risk people. In particular, we propose to leverage an existing network of diverse primary care practices, to integrate a SDM tool (CV PREVENTION CHOICE) into their EHR, and to identify the factors that facilitate its routine use. We will also assess its effectiveness in addressing the risk-treatment paradox. In this protocol, “primary care” refers to clinical settings in which patients without a history of cardiovascular events discuss and form plans of preventive care to reduce cardiovascular risk with their clinicians.

This study's significance resides on its ability to leverage a network of practices, deploy an EHR-enabled and effective CV decision tool, and mobilize state-of-the-art methods to identify how best to implement SDM in a manner that effectively and efficiently reduces the burden of CV disease on Americans. Its strengths include (1) its systematic but flexible approach to tracking implementation strategies in real-world practice and at intervals that allow for identification of strategies that made a difference, (2) the inclusion of an implementation step-down period for assessing SDM after implementation support is removed—a critical factor when considering how to routinize SDM—(3) the availability of EHR functionality to assess adoption and use, and (4) the use of theory-driven mixed methods. These strengths are in contrast to existing literature on SDM in CV health that is limited to research in single settings or settings that do not represent real-world practice, research that relies singularly on users to identify factors related to implementation success or to determine adoption and use, and research that fails to employ theory to assess multilevel implementation factors.

3.0 Preliminary Work

3.1 Development of SDM tools

For the last 15 years, this team has been employing person-centered design to produce SDM interventions, implement them in clinical workflows, and test them in pragmatic randomized trials (RCTs). Overall, these tools have proven effective in helping clinicians communicate estimated individualized risk with patients, consider the value of interventions that can mitigate this risk, and determine whether the potential harms, inconveniences, and costs are worth the potential benefits.

The SDM tool employed in this trial—CV PREVENTION CHOICE—is based on the Statin Choice SDM tool, which was created in 2005 and has been evaluated in three RCTs. This SDM tool assists clinicians estimating and displaying each person's CV risk (using the pooled ASCVD equation, Framingham, or Reynolds) and in developing a plan of care (based on efficacy, safety, costs, and inconveniences) to address this threat. The tool uses a risk communication approach combining best practices that reaches people with varying levels of numeracy, those who seek detail and those who are satisfied by gist. Clinicians explain the risk display emphasizing (a) the passage of time, (b) the likelihood of outcomes in “patients like you,” and (c) the uncertainty for the individual. Then, it shows the plan's impact, were it implemented, on the patient's estimated CV risk. This phase of the discussion ensures that the evidence-based preventive strategy under consideration makes sense, is consistent with the values and preferences for prevention of each patient and is feasible in the biological and socio-economic contexts of the patient, all issues about which the patient has an irreplaceable perspective and expertise. Supported by “live” systematic reviews, the tool considers the risk-reducing effects of the interventions discussed in the ACC/AHA 2019 Primary CV Prevention Guidelines including smoking cessation, diets (DASH, Mediterranean/, low-carbohydrate), physical activity, cholesterol-lowering drugs (e.g., statins, ezetimibe), blood pressure control and specific agents (e.g., diuretics, ACE inhibitors), and glycemic control and specific agents (e.g., SGLT-2 inhibitors, GLP-1 analogues). A common limitation of existing tools is the use of epidemiological association (rather than RCT-derived estimates of efficacy when available) to model (using what-if exercises) the

impact of the treatment program on CV risk. Our tool takes a novel approach by fostering the development of a feasible plan of care first and then showing its impact on risk based on the best evidence available. The process is repeated until patients and clinicians arrive at a feasible and sensible plan. The STATIN CHOICE SDM tool has been shown to improve risk understanding (OR: 6.7, 95% CI 2.2, 19.7), to correct the risk-treatment paradox (e.g., reducing by 70% the prescription of statins among low risk patients), and to improve self-reported adherence to statins by 3-fold.⁹

3.2 Implementation of SDM tools

Based on the results of efficacy trials in Minnesota, Spain, and New York, we sought to understand the challenges of implementing the Statin Choice SDM tool within the electronic workflow at three diverse health systems in North Dakota, Missouri, and Idaho.¹⁰ Each clinic offered a diverse array of factors to promote or hinder the implementation of our CV prevention SDM tool including support from the c-suite leaders (including contracting and quality improvement leaders), the IT department, and frontline clinician champions. We conducted a rigorous theory-driven implementation science mixed-method study in which we followed the adoption and normalization achievements at each site. What we learned from this study is that integration into the EHR of an SDM tool is necessary but not sufficient for its sustained use in the clinical encounter. In particular, the electronic integration supported the automatic population of the risk calculator and the display of risk and options within the EHR. This integration plus a passive implementation strategy achieved suboptimal reach and failed maintenance. Thus, we learned that integration into the EHR alone is not enough to increase the adoption of the SDM tool and sustain its proper use in usual clinical practice. With the current study, we will start with IT integration of the SDM tool (CV PREVENTION CHOICE) in every site, such that the focus of the study can be on integration within the clinical workflow according to local constraints and conditions and normalization of CV prevention discussions of clinicians with their at-risk patients.

4.0 Research Design & Methods

4.1 Overview

This is a mixed method, Hybrid Type III step-wedge cluster randomized study to estimate (a) the effectiveness of implementation strategies on SDM uptake and utilization, and (b) the extent to which SDM results in prevention plans that are congruent with risk. Prioritizing evaluation of the implementation of our SDM tool is appropriate in light of the robust evidence for the tool's effectiveness and the need for stronger implementation evidence. The study employs three theoretical approaches: a determinant framework that calls attention to categories of factors that may foster or inhibit implementation outcomes (the Consolidated Framework for Implementation Research [CFIR])¹¹; an implementation theory that guides explanation or understanding of causal influences on implementation outcomes (Normalization Process Theory [NPT]),^{12,13} and an evaluation framework that will be used to assess implementation success (RE-AIM).¹⁴

4.2 Schema

The step-wedge design will be implemented across three health systems, indicated in Figure 1 by N1, N2, and N3. The order of implementation will be randomized by the

study statistician. All health systems will have a minimum of six months of usual care, followed by active implementation and maintenance (step down) periods.

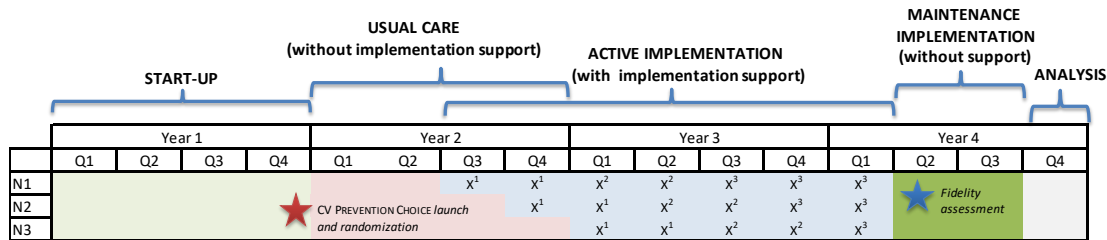


Figure 1: Step-Wedge implementation timeline

The implementation and evaluation approach is shown in Figure 2. Developmental formative evaluation work will take place before CV PREVENTION CHOICE is implemented in the health systems. The aim of this work will be to identify and address factors likely to impact feasibility, acceptability, and adoption of CV PREVENTION CHOICE, and to optimize implementation strategies for success. Implementation-focused formative evaluation will be employed during the active implementation stage in order to facilitate stakeholder engagement and responsiveness to implementation challenges, as well as document adaptations/fidelity.

Finally, because this is a hybrid trial, there are both implementation outcomes (e.g., how well was the tool adopted by clinicians) and effectiveness outcomes (e.g., did the tool lead to risk-concordant treatment plans). The evidence of implementation strategy effectiveness will be a key outcome that can be shared with other health systems.

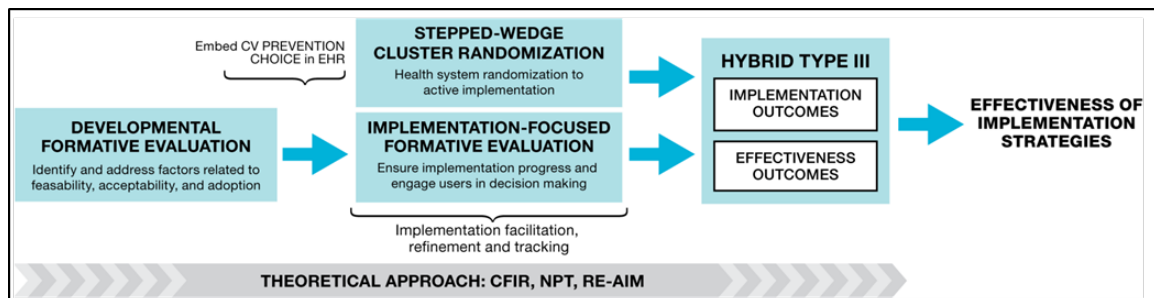


Figure 2: Implementation and evaluation approach

4.3 Phases of study

Phase 1: Start – up

The first stage across all clusters will serve the purpose of study set-up (e.g., IRB protocols and approvals), development and organization of the implementation facilitators and implementation board across systems, and development of IT and data processes required for deployment of CV PREVENTION CHOICE, including EHR governance in the health systems. To facilitate this process, we have allocated funding for the local IT team, selected sites that use the EPIC EHR, scheduled this effort to take place over 12 months, and prepared CV PREVENTION CHOICE for EPIC implementation by “wrapping” it in the SMART on FHIR standard. Local IT will ensure data fields are mapped to data sources for each element necessary for CV risk calculation, that the

application can be triggered within locally defined clinical workflows, and that they can integrate its reporting feature into the portal function.

Phase 2: Usual Care

EHR deployment will mark the transition to the usual care stage. During this stage, no ‘active’ notification or clinician training will take place, mimicking the conditions under which many decision support tools exist, i.e., available in the EHR without support or integration into clinical workflow. From an implementation perspective, this stage will be used to train the internal implementation facilitator and develop initial strategies for the first implementation interval in each cluster. These decisions will be informed by the contextual data collected during the start-up stage.

Phase 3: Active Implementation

The active implementation stage, rolled out at randomly assigned intervals, will involve on-going implementation support. Sites will also be engaged in assessing implementation and identifying implementation strategies based on local needs. Sites will assess and adapt their strategies at defined intervals. Intervals will typically be no less than 3 months in order to allow time for assessment, and generally they will be 6 months. Portrayed as implementation dose changes, each interval marks strategy refinement, which may include adoption or de-adoption of individual strategies.

Phase 4: Maintenance Implementation

The end of active implementation leads to the final stage (maintenance implementation), during which we will evaluate sustainability of the intervention (and fidelity of use) and implementation strategies, to determine the extent to which normalization of the SDM tool in routine practice is possible.

4.4 Study Setting and Participation

4.4.1 Health Systems

This study will take place in the Mayo Clinic Care Network (MCCN) and the Mayo Clinic Health System (MCHS). The MCCN is a collaborative network linking more than 40 health systems around the globe with research, education, and clinical expertise of Mayo Clinic. MCCN sites care for thousands of patients in academic and community-based environments and within varied organizational delivery models, payment schemes, and geopolitical contexts and settings. The MCHS consists of Mayo Clinic community primary and specialty practices in the Midwest.

Inclusion Criteria:

- Health systems in the MCCN or MCHS using the EPIC EHR
- Enroll and support a minimum of 4 participating care sites with at least five clinicians at each site
- Provide prioritized IT support to integrate and maintain CV PREVENTION CHOICE within the EPIC EHR, and implement data abstraction procedures to minimize manual data collection

- Support staff to champion implementation facilitation and data collection at the sites, including interviews and surveys used to assess implementation outcomes

4.4.1.1 Recruitment of Health Systems

Health systems that meet eligibility criteria will be contacted via the MCCN or study team leadership and inquiries of interest to participate will be made. If an initial interest is expressed the study team will provide an overview of the study along with a presentation if requested.

4.4.2 Sites for Health Systems

Each health system will evaluate their sites to assess where care for these patients is being provided. If the site meets eligibility criteria of at least five clinicians and regularly see adult patients 40-75 for preventive care then the health system can choose for that site to participate.

4.4.2.1 Recruitment of Sites

The study team will work with the health system champion to identify each site that meets eligibility criteria. The site champion, with assistance from the study team, will present the project to clinicians and other key stakeholders (e.g., administrators) at the site.

4.4.3 Clinicians

The clinicians and stakeholders (e.g. administrators) who agree to participate in the trial will be asked to complete surveys and participate in qualitative individual or group interviews. Clinicians may also be asked to participate in the audio-/video-recording of a sample of clinical visits to assess fidelity in the use of the shared decision making tool in conversations with patients during routine care. All clinicians in these systems (physician, advanced practice provider, etc.) who are affiliated with identified practices and who participate in the care of adult patients eligible for CV primary prevention will be invited to participate.

4.4.3.1 Clinician Recruitment

Clinicians will be approached for participation during the presentation of the study to the sites or in individual conversations with members of the study team. For collection of data on encounters, all clinicians that are eligible from participating sites will have their encounter data abstracted to assess outcomes of interest.

4.4.4 Study Subjects (Patients)

Eligible patients are selected following the 2019 ACC/AHA guidelines for CV primary prevention.

Inclusion criteria:

- Age 40 to 75
- With or without diabetes

- Receive preventive care in the affiliated practices during the course of the study.

Exclusion criteria:

- Experienced a first atherothrombotic clinical event

We anticipate that some otherwise eligible patients will not participate in preventive care because of advanced disease, limited life expectancy, or any other condition that makes focusing on CV prevention inappropriate. As part of the implementation outcomes we will monitor for the exclusion of persons from SDM for any reason, including insufficient vision or cognition.

4.4.4.1 Study Subject Recruitment

Health record data for eligible patients who have encounters during our phase 2, 3, and 4 will be abstracted to assess Aim 2 effectiveness outcomes, as well as analyses of Aim 1 implementation outcomes that involve patient diagnosis or demographic information. For these data, patients will not be approached for inclusion, but instead eligible encounters will be abstracted for research purposes and direct identifiers of patients will be removed (names, dates, and emails). We will follow any local policies for data authorization, e.g., Minnesota Research Authorization.

A sample of eligible patients will be recruited for audio-/video-recording of clinical encounters in which fidelity of the tool is assessed. Calendars of participating clinicians will be screened for eligible patients. Study personnel will assess eligibility and notify participating clinicians of eligible patients with upcoming appointments. Clinicians will have an opportunity to express their agreement in having these patients approached for participation in recorded clinical encounters. Patients will be approached by trained study personnel once they have been roomed for their appointment, prior to the clinical encounter. Those patients will also be asked to complete a survey to assess perspectives of the quality of SDM in the encounter. Patients who are eligible to participate in the audio-/video-recording and survey portion of the study will be approached to assess study interest. For those who are willing to participate, trained study personnel will complete written consent procedures in a private location (such as an exam room) post-intake, pre-encounter. We anticipate three days of recording in each health system, with approximately 10 patients per day eligible to be approached for participation. For guests present at clinical encounters, an oral permission script will be used (listed under Supporting Documents of the IRB application).

4.5 Description of the Intervention

4.5.1 CV PREVENTION CHOICE

The 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease recommends that “Adults who are 40 to 75 years of age and are being evaluated for cardiovascular disease prevention should undergo 10-year atherosclerotic cardiovascular disease (ASCVD) risk estimation and have a clinician–patient risk discussion.” The CV PREVENTION CHOICE SDM tool operationalizes this recommendation and makes it possible to implement it in routine care, in accordance with these guidelines’ preamble: “Adherence to recommendations can be enhanced by shared decision-making between clinicians and patients, with patient engagement in selecting interventions on the basis of individual values, preferences, and associated conditions and comorbidities.” This endorsement of SDM receives the strongest, Class I recommendation: “Shared decision-making should guide discussions about the best strategies to reduce ASCVD risk” and continues “Decisions about primary prevention should be collaborative between a clinician and a patient. Shared decision-making occurs when practitioners engage patients in discussions about personalized ASCVD risk estimates and their implications for the perceived benefits of preventive strategies, including lifestyle habits, goals, and medical therapies.”

The CV PREVENTION CHOICE SDM tool is based on the Statin Choice SDM tool, which was created in 2005 and has been evaluated in three RCTs. This SDM tool assists clinicians estimating and displaying each person’s CV risk (using the pooled ASCVD equation, Framingham, or Reynolds) and in developing a plan of care (based on efficacy, safety, costs, and

inconveniences) to address this threat. The tool uses a risk communication approach combining best practices that reaches people with varying levels of numeracy, those who seek detail and those who are satisfied by gist. Clinicians explain the risk display emphasizing (a) the passage of time, (b) the likelihood of outcomes in “patients like you,” and (c) the uncertainty for the individual. Then, it shows the plan’s impact, were it implemented, on the patient’s estimated CV risk. This phase of the discussion ensures that the evidence-based preventive strategy under consideration makes sense, is consistent with the values and preferences for prevention of each patient and is feasible in the biological and socio-economic contexts of the patient, all issues about which the patient has an irreplaceable perspective and expertise. Supported by “live” systematic reviews, the tool considers the risk-reducing effects of the interventions discussed in the



ACC/AHA 2019 Primary CV Prevention Guidelines including smoking cessation, diets (DASH, Mediterranean/, low carbohydrate), physical activity, cholesterol-lowering drugs (e.g., statins, ezetimibe), blood pressure control and specific agents (e.g., diuretics, ACE inhibitors), and glycemic control and specific agents (e.g., SGLT-2 inhibitors, GLP-1 analogues).

4.5.2 Implementation Strategies

The primary implementation strategy in this study is implementation facilitation. Facilitation is an approach that puts primary value on the active engagement of stakeholders to develop and problem solve implementation strategies based on local context. Each system will be asked to identify an internal implementation facilitator (IIF). This person will be responsible for helping the study team assemble the local resources to implement the intervention (e.g., administrators, IT personnel, and clinician leaders) and supporting selection and deployment of the implementation strategies. They will also complete facilitation tracking. During study start-up and usual care, the IIF will be involved in formative evaluation strategies, e.g., assessing readiness to implement the intervention. A member of the study team will serve as the external implementation facilitator (EIF). In this role, he or she will provide implementation facilitation training and ensure adequate implementation knowledge and support at the system and site levels. The EIF, along with the statistician, will also provide the local team with data or other information (e.g., metrics on tool use, results of surveys) that can assist with local implementation decision making.

During the active implementation stage, these individuals, with the support of other members of the study team and health systems, will assess and respond to implementation progress (e.g., qualitative assessments of challenges) and outcomes (e.g., metrics of tool adoption) to identify ways to further tailor implementation strategies. To allow adequate time to deploy and assess individual changes to local implementation strategies, local implementers will convene to review local data and take actions (including adoption, de-adoption, and maintenance of individual strategies) at approximately six-month intervals. All decisions and their timing will be tracked by the IIF (using a tracking log) to facilitate evaluation. These logs will document implementation decisions and changes in implementation strategies and serve to estimate the bundles of strategies implemented each interval (i.e., the “dose” of implementation effort).

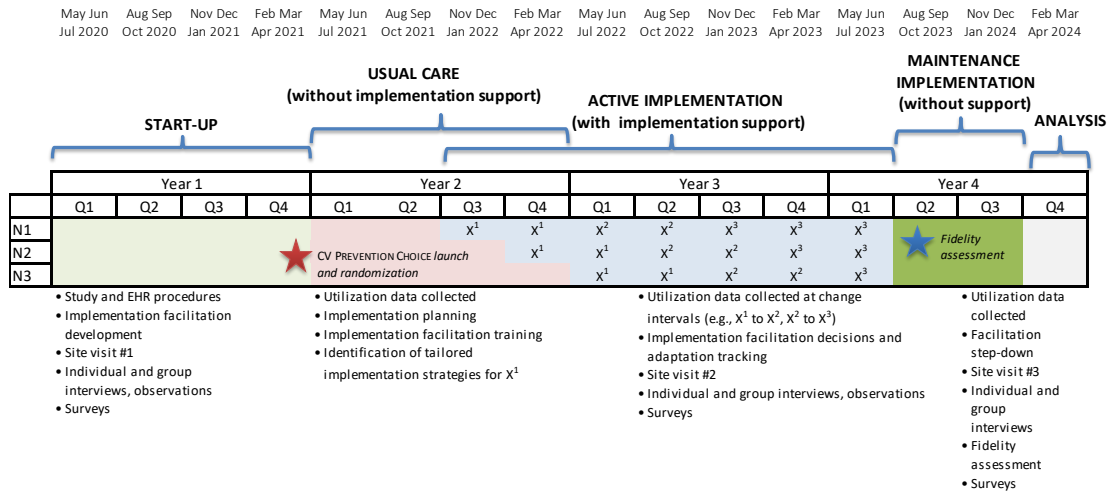
4.5.3 Structure of the study team

The health systems have representation on the trial steering committee (Co-Investigators). The study team will meet with key personnel in the health systems as needed during the first year and approximately monthly in subsequent years. The trial steering committee will meet as needed. Email and other asynchronous communication will be used to update the steering committee on study progress between meetings.

While most implementation work will happen at the system or site level, work will be guided at the study level by an implementation board, which will include representatives from each system and members of the study team (e.g., representatives with expertise in implementation, SDM deployment, and statistics/data transfer). The board will support implementation of the SDM intervention (e.g., supporting technology-related implementation decisions) at the system level, as well as provide overall study

guidance as it relates to implementation strategies and study procedures (e.g., secondary data abstraction and primary data collection). During the planning stage, the board will be primarily focused on facilitating development of the EHR deployment and procedures for data collection. Board meetings will take place at regular intervals (determined by study stage) using virtual meeting technology. The implementation board will meet approximately quarterly. Meetings will be held virtually, unless there is a need to meet in person.

4.5.3 Study activities / timeline



Phase 1 - Start-up: The start-up phase will take place during Year 1 (for all three health systems). During this phase, the health systems will identify internal implementation facilitators (one per health system unless one per site is more feasible), and key personnel for IT and data systems development. Tasks during this phase include:

- Recruiting health system sites
- Identifying health system and site champions (i.e., individuals who help build relationships and create buy-in)
- Identifying health system (and/or) site internal implementation facilitators
- Developing study procedures and procuring human subjects approvals
- Developing procedures and IT systems for integration of CV PREVENTION CHOICE in the EHR and abstraction of data for analysis
- Facilitating any necessary EHR and data governance activities in the health systems
- Study team conducting site visit #1 (of 3) and observations of clinic practices
- Development of implementation facilitation resources and education by study team
- Surveys and individual or group interviews with health system and site personnel to assess readiness and barriers/facilitator to implementation, as well as perspectives on SDM

Phase 2 - Usual care: EHR deployment will mark the transition to the usual care stage. We anticipate Epic integration will happen at similar timeframes across health systems, but the length of the usual care period will depend on when a health system is randomized to active implementation. During the usual care stage, no ‘active’ notification or clinician training will take place, mimicking the conditions under which many decision support tools exist, i.e., available in the EHR without support or integration into clinical workflow. Tasks during this phase include:

- Training for internal implementation facilitators (virtual) by the external implementation facilitator (EIF)
- Identification and preparation of initial implementation strategies for the first randomized health systems sites, tailored to the results of the start-up stage assessment for that site (e.g., results of surveys, interviews/focus groups, site visits) (IIF and EIF)
- Continued refinement of IT systems and data collection procedures

Phase 3 - Active Implementation: In this study, the intervention period refers to the period during which a health system is engaged in active implementation strategies to increase adoption of CV PREVENTION CHOICE. The active implementation stage, rolled out at randomly assigned intervals, will involve on-going implementation support, assessment of implementation successes and challenges, and refinement of implementation strategies to meet local needs. In contrast to the usual care stage, when the SDM tool is available but not promoted, during this phase the study will be aimed at increasing adoption and use and studying implementation strategies to see what works. Tasks during this phase include:

- Assessment of SDM tool utilization using EHR metrics
- Assessment of perspectives of health system and site personnel using surveys and individual or group interviews
- On-going tracking of implementation strategies by the internal implementation facilitator (e.g., log of presentations, education sessions, one-on-one clinician training)
- At appropriate intervals (i.e., implementation dose changes), the study team will convene local stakeholders to assess barriers to adoption and refine implementation strategies to be responsive to local needs
- Study team site visit #2 (of 3) and observations of clinic practices

Phase 4 - Maintenance Implementation: The maintenance period marks implementation step-down and assessment of normalization of SDM into practice (i.e., routine, sustainable use without implementation support). Tasks during this phase include:

- Sample of patients (approximately 27-36 across the three health system) recruited to participate in video recording of clinical encounter, as well as post-encounter surveys.
- Study team will review video recording as part of an assessment of intervention fidelity (i.e., how clinicians using CV PREVENTION CHOICE in SDM encounters)
- Study team site visit #3

- Assessment of perspectives of health system and site personnel using surveys and individual or group interviews

4.6 Data Collection

4.6.1 Data Collection – Aim 1:

Specific Aim 1 involves a multilevel evaluation of:

- Practice context (e.g., potential barriers to implementation);
- Implementation outcomes (e.g., reach, adoption) that provide evidence of which tailored implementation strategies were most effective; and
- The work clinicians do to normalize use of the SDM tool in routine practice.

Data collection includes surveys, qualitative methods such as interviews/focus groups, and the use of metrics from the EHR. It will involve clinicians, key stakeholders in the health systems, and patients. Data collection will occur in each phase, as described below and summarized in the following table.

Prior to a scheduled interview/focus group, a variety of techniques will be utilized to remind participants of their upcoming interview/focus group. Depending on participant preference, they will be able to choose the method in which they are reminded: by telephone, by text message to a mobile device, or by e-mail. Participants will also be given the option of having a calendar invitation sent to them to remind them of their upcoming interview/focus group. E-mail address will be collected for participants who opt to have an e-mail reminder and/or calendar invitation sent to them. For participants who elect to have their reminder sent by text message, we will collect phone carrier information (this data is needed for determining the appropriate SMS gateway domain). Characteristic surveys will also be collected at the health system and site level. These surveys will be completed by the health system champion and the site champion, respectively. The health system survey will be administered during the start-up phase to capture number of physicians, patients, bed, practices within the system as well as the number of years they have been on Epic. The site survey captures the practice type, the number of physicians, average number of encounters per week and average length of appointments. The population of the community the site resides in is captured as well.

Construct	Method (Participants*)	Stage			
		Start-up	Usual Care	Active Implement.	Maint. Implement.
Attitudes about SDM	Survey related to SDM attitudes (Clinicians)	X		X	
Potential barriers to implementation	Survey related to organizational readiness (Clinicians and stakeholders)	X			
Perceptions of SDM	Individual or	X		X	

and the implementation context	group interviews (clinicians and stakeholders)				
REACH:** willingness to participate	EHR metrics		X	X	
EFFECTIVENESS:** perceptions of whether the tool is effective	Individual or group interviews (clinicians)			X	
ADOPTION:** proportion of tool use and factors affecting adoption	EHR metrics and individual or group interviews (clinicians)			X	X
IMPLEMENTATION (fidelity):**adherence to SDM best practice delivery	CARE Measure and Shared Decision Making Questionnaire-9 (Patient sample) Fidelity checklist (sample of video-recorded clinical encounters) Individual or group interviews (clinicians)				X
MAINTENANCE** and normalization of SDM in routine practice: sustainability of SDM practice	NoMAD questionnaire (clinicians and stakeholders) PRESS questionnaire (Clinician and Stakeholders)			X	X

*Stakeholders will be identified by health systems but may include clinic administrators, physician leaders, IT leadership, etc.

** Part of the RE-AIM implementation outcomes

Phase 1 - Start-up:

Clinician and stakeholder surveys: Two surveys will be administered during the start-up phase, one to clinicians and one to organizational stakeholders, e.g., leaders in research, IT, and administration. The clinician survey will explore participants' understanding of SDM and their attitudes toward SDM in relation to time constraints, liability, conflict with clinical judgment or guideline recommendations, and decisional responsibility. Both the clinician and stakeholder survey will also address perspectives on appropriateness and feasibility at the organizational level. All eligible clinicians and key stakeholders (identified by local IIFs) will be invited to participate in surveys. Surveys will be administered electronically (Qualtrics, Provo, UT). The study team will work with the champions at each health system to ensure the list of email addresses is available. If a response is not received by the second reminder then a paper survey will

be delivered to the participant for completion. Paper surveys will be data entered for analysis.

Clinician and stakeholder interviews or focus groups: Individual or group interviews with clinicians and other stakeholders will be held in person or by phone or video conference. All eligible clinicians and key stakeholders (identified by local IIFs) will be invited to participate. We aim to complete individual or group interviews with at least 15 clinicians and 12 key stakeholders (total across the three health systems) during the start-up phase. Interviews will be conducted by a trained member of the study team using a semi-structured interview guide, recorded with permission, and transcribed verbatim and de-identified for analysis. A trained member of the study team will assist with recruitment and oral consent to participate in interviews, and all data will be stored on a password-protected server. Observation during study start-up will also help characterize the implementation context and existing clinic workflow.

Phase 2 - Usual care:

During the usual care phase, data collection will only include the use of EHR metrics to assess REACH (proportion of clinicians who accessed CV PREVENTION CHOICE; characteristics of participants versus non-participants). This assessment during usual care will provide information about clinician adoption absent the use of implementation strategies. EHR data used to assess implementation outcomes in Aim 1 will be abstracted using the same approach outlined below for Aim 2.

Phase 3 - Active implementation:

Clinician surveys: A clinician survey will be administered a second time during the active implementation stage. We will also administer the NoMAD questionnaire¹⁶⁻¹⁸ to understand how well SDM has been normalized into routine clinical practice. NoMAD questions are grouped in domains representing the constructs of NPT, which together provide a framework for understanding how an intervention is implemented, embedded, and integrated into practice: Coherence (e.g., “I can see the potential value of the [intervention] for my work”), Cognitive Participation (e.g., “I believe that participating in the [intervention] is a legitimate part of my role”), Collective Action (e.g., “I can easily integrate the [intervention] into my existing work”), and Reflexive Monitoring (e.g., “I value the effects the [intervention] has had on my work”). Survey procedures will mimic those outlined for start-up phase surveys.

Clinician and stakeholder interviews or focus groups: Group or individual interviews will also be conducted during the active implementation stage. The interview guide will further assess constructs including acceptability, but also seek to understand challenges to implementation. Interview procedures will mimic those outlined for start-up phase surveys. We aim to complete individual or group interviews with at least 30 clinicians and 12 key stakeholders (total across the three health systems) during the active implementation phase.

EHR metrics: Assessment of EHR metrics for REACH (proportion of clinicians who accessed CV PREVENTION CHOICE; characteristics of participants versus non-participants) and ADOPTION (proportion of eligible clinicians who used CV

PREVENTION CHOICE) will continue throughout the active implementation and maintenance phases, using the same data abstraction procedures outlined for Aim 2.

Phase 4 - Maintenance implementation:

Clinician and Stakeholder surveys: The NoMAD survey will be repeated with clinicians and conducted with other key stakeholders during this phase, using the same survey data collection procedures outlined above. The Provider REport of Sustainment Scale (PRESS) survey will be administered at this time as well, to assess the sustainment of the intervention.¹⁹

Clinician and stakeholder interviews or focus groups: Interviews or focus groups with clinicians and other stakeholders at this stage will focus on normalization of SDM into routine practice, using constructs from the NoMAD questionnaire as a guide. We will also ask participants to self-report any adaptations to the interventions, as part of the fidelity assessment. All clinicians and a sample of key stakeholders will be invited to participate and data collection will follow procedures outlined above. We aim to complete individual or group interviews with at least 20 clinicians and stakeholders (total across the three health systems) during the maintenance phase.

Video-recorded encounters and patient surveys: A sample of patients will be recruited for fidelity assessment. This will involve video recording of clinical encounter and completion of a post-encounter survey with questions about cardiovascular risk perceptions, as well as items from two validated measures: 1) the CARE Measure,²⁰ and 2) the Shared Decision Making Questionnaire-9.²¹ For patients that agree to participate, demographic and clinical information will be captured from the EHR. Recording and surveys will take place in-person in the clinical setting. Surveys will be completed on paper and data entered REDCap or using electronic data capture systems (e.g., REDCap survey on a clinic tablet). We anticipate approximately 10 eligible encounters per day (per system/site). Our experience in similar studies suggests we will be able to recruit and enroll in about one-third of eligible encounters (3 or 4 visits). This will yield approximately 27 to 36 audio-/video-recorded files for analysis across the three health systems. Recruitment and written consent will be conducted in-person by a trained member of the study team. For guests present at clinical encounters, an oral permission script will be used (listed under Supporting Documents of the IRB application).

4.6.2 Data Collection – Aim 2:

Aim 2 estimates the extent to which CV Prevention Choice, as implemented in community settings, results in individual CV prevention plans that are evidence-based, congruent with each person's estimated CV risk, and feasible within each patient's personal and psychosocial context. This aim utilizes data from the EHR, as outlined in the following table. Specifically, from the EHR, each healthcare system will provide a unique patient identifier that does not identify the patient in any manner (i.e. create a random digit identifier and they will house the key to it). Along with this identifier, each health system will provide in monthly data submissions the date of the encounter, the clinician that the patient saw, and EHR data.

Data Item	Definition
Patient Identifier (random, unique)	To identify multiple encounters per patient.
Date of index visit	Indicator of time in relationship to implementation.
Clinician Identifier	Used to identify multiple encounters, tool usage to assess Reach, Adoption.
Gender	Patients gender
Age, Race	Descriptor, used in risk calculation, patient covariate for adjusting model.
Ethnicity	Patient covariate for adjusting and describing population.
Insurance	Patients most recent insurance status categorized as: Private, Medicare, Medicaid, Government, Other or None. If a patient has more than one category listed, then all categories applicable to that patient will be captured.
Smoking Status	Most recent smoking status captured along with date of capture. Used in risk calculation.
Diabetes, Hypertension	Descriptor, used in risk calculation, current diagnosis or previous 12 mo.
Cholesterol (total, HDL), systolic blood pressure, coronary calcium score, Lipoprotein	Most recent documented value.
CV risk calculation	To assess risk concordance with usage.
Top 2 index visit diagnoses	Proxy for reason of visit.
Index visit clinical note	Indicators of shared decision making.
SDM tool use	Indication of use of tool and components, decision made.
Current medication use	Current use/prescription for pharmacological preventive interventions
Visit Mode	In person, on video or a phone call.

4.7 Analysis Plan

4.7.1 Data Analysis – Aim 1

Surveys will be analyzed using descriptive statistics at the system level. Other secondary analyses (e.g., by site) will be completed as appropriate based on response. Response rates and unadjusted average estimates along with standard deviations for each system will be presented. As participants within a healthcare system may have similar responses, a clustering effect due to proximity, shared administration, and similar exposure to adopted active implementation strategies the analysis will account for this clustering effect.

Qualitative data, e.g., interview transcripts, will be subject to directed content analysis by at least two study team members. Directed content analysis takes into consideration the existing literature and theories or frameworks that informed the research, e.g., CFIR. Computer-assisted qualitative data analysis software (NVivo 12.3., QSR International) will facilitate data organization, including analytic memo writing that summarizes impressions and explores and documents connections in the data. To inform implementation strategy decisions, the implementation teams will review survey data and qualitative memos. They will use collaborative meetings to map identified determinants or contextual barriers to potential strategies that address them.

For measures of adoptions, we will use data from the EHR to determine the proportion of eligible clinical visits (in accordance with the 2019 ACC/AHA guidelines for the primary prevention of CV disease, patients aged 40-75 will be evaluable) in which CV PREVENTION CHOICE was recorded as being used. IMPLEMENTATION (FIDELITY) will be assessed in the transition to the maintenance implementation stage in three ways. First, we will video-recorded clinic visits and assess fidelity to core components of SDM clinical conversations.²² Second, for video-recorded encounters, we will ask patients to complete two surveys related to SDM and patient-centered care: the CARE Patient Feedback Measure²⁰ and the Shared Decision Making Questionnaire (SDM-Q-9).²¹ Finally, individual and group interviews with clinicians and stakeholders will be used to capture self-reported adaptations made to the use of CV Prevention Choice in practice. MAINTENANCE will be assessed by determining CV Prevention Choice use at the end of the maintenance implementation period for each cluster.

The rate of CV Prevention Choice use will be assessed using descriptive techniques. For REACH, we will calculate the proportion of clinicians who activated the tool link (from among clinicians who had an eligible visit during that period). These results will orient outreach efforts by local teams. At the end of active implementation, participation rates will be compared on two characteristics (practice type and job classification). For ADOPTION, we will calculate the proportion of eligible clinical visits at each site where tool use was documented in the EHR; the difference in adoption at the midpoint of usual care and at every six months and at the end of the active implementation stage will reflect the difference between simply embedding the tool in the EHR and full implementation of tailored strategies. To further assess the impact of iteratively refining implementation strategies, we will identify—using the tracking logs and qualitative data—those strategies that were employed during each implementation 6-month implementation change interval. As a proxy for clinicians' long-term use and perceived value (MAINTENANCE)—even in the absence of active implementation support—we will evaluate the proportion of eligible visits during which CV Prevention Choice was used repeatedly with the same patient.

For IMPLEMENTATION (fidelity), two trained members of the study team will work in duplicate to review recordings against a fidelity checklist. In any cases where there is lack of concordance, a third trained member of the study team will arbitrate. Patient post-encounter surveys will be analyzed descriptively by site and system to understand fidelity to components of SDM conversations. Qualitative data from individual or group interviews—including those related to EFFECTIVENESS—will be analyzed using methods of content analysis. In this analysis we will further use side-by-side comparisons of qualitative and quantitative findings.

4.7.2 Data Analysis – Aim 2

For each encounter that is evaluable for assessment, the outcome of interest for Efficacy will be coded as a binary outcome (Indication of Medication usage in EHR – any, can be 1 medication or all three). This outcome will be assessed using a risk adjusted mixed logistic regression model. The model will adjust for each patient's CV risk score – akin to adjusting the model for case-mix taking into account the risk of death to appropriately estimate differences found assessing quality of hospitals on mortality. The model will account for the potential clustering effect that would be expected among

patients along with clinician and practice within the health system (random effect, to account for correlation of patients with multiple encounter, patients seen by the clinician and clinicians within practices, with the inclusion of practices as there could be variation among sites within a system), roll-out time period (fixed effect, to adjust for confounding of intervention with time trends), and tool usage variable (fixed effect, usual care vs CV Prevention choice, the effect of interest).²³ Patient and site covariates will be included to adjust for differences in patients and sites across units and over time. Model assumptions will be verified and findings will be reported according to best practices including CONSORT guidelines on cluster randomized trials. In secondary analyses, the models will be extended using interaction terms to examine several types of heterogeneity of treatment effect (HTE) due to possible changes or improvements in effectiveness of the intervention (interaction of intervention with time period). One secondary analysis is the interaction between tool use and the time interval (starting at passive implementation in EHR and increased by quarter till the start of maintenance, to assess if there are different effects of usage depending on the time point. Although we do not hypothesize difference by sex or race, additional HTE to be evaluated include potential interaction effects among patient sex and patient race (minority vs. not). These will be reported in study findings as appropriate.

Sex as a biological variable (SABV): The central hypothesis of this study is that there is a risk-treatment paradox that SDM can overcome. The SDM intervention presents a calculated CV risk estimate. Sex (along with age) is a large contributor to this calculation. The SDM intervention then seamlessly provides this estimate, which differentiates on and accounts for the effect of sex, without disrupting the flow of conversation. Furthermore, the SDM tool includes information where a CV risk reduction-sex interaction exists (e.g., aspirin for primary prevention of strokes). We will conduct the abovementioned explorations of treatment-subgroup interactions, including interactions by sex. Gender is also associated with disparities in risk-concordant treatment planning. Thus, our intervention and analysis plan seek to directly address sex-related disparities in CV risk reduction and to explore an interaction of the intervention effect with sex.

4.7.3 Sample Size Estimation

Statistical power was estimated for the Aim 2 effectiveness outcome only. Aim 1 evaluation samples are based on the number of clinicians or other stakeholders we expect to enroll, based on the minimum numbers of clinicians in the sites from participating health systems. While sample sizes for qualitative inquiry are not dictated by statistical power analyses, the expected numbers of individual or group interviews are well within the parameters for qualitative content analysis and should be sufficient for qualitative assessment of factors related to implementation. Similarly, survey analysis will be largely descriptive (to understand implementation) and will be undertaken with appropriate statistical considerations in mind. Any limitations will be reported alongside results as appropriate.

For Aim 1 fidelity assessments, we anticipate approximately 10 eligible encounters per day (per system/site). Our experience in similar studies suggests we will be able to recruit and enroll in about one-third of eligible encounters (3 or 4 visits). This will yield approximately 27 to 36 audio-/video-recorded files for analysis across the three

health systems. Two members of the study team (who have been trained in the use of the fidelity checklist and have background in shared decision making research) will work in duplicate to review the recordings against the fidelity checklist. In any cases where there is lack of concordance, a third trained member of the study team will serve to arbitrate. In this study the purpose of the fidelity checks is to understand how clinicians are using the CV Prevention Choice tool for shared decision making, not to assess differences between intervention and usual care groups. Thus statistical power considerations are not applicable.

For Aim 2, we estimated the intervention effect that can be detected with our stepped wedge design on proportion of patients with a medication of interest on record to be detectable at a 10% increase over usual care with the CV Prevention Choice tool. We assumed the following: 1) there will be > 400 evaluable patients per rollout in a health system during the study period (I.e. 1600 patients per health system with a total of 4800 encounters evaluable), 2) the intracluster correlation (ICC) is 0.10 with a between cluster variation of 0.025, 3) a two-sided level 0.05 significance tests. The estimate of patients seen per health system is based on previous work to implement Statin Choice, where we saw a mean of 300 uses per month in each of three health systems, although this does not account for encounters in which the tool was not used. Using methods for estimating sample size, we estimate 97% power to detect the 10% increase in medications being recorded/prescribed in the EHR. Our estimate is consistent with a Cochrane systematic review of interventions to improve adherence to lipid lowering medications, which found improvement in interventions that involved simplification of the drug regimen (absolute adherence increase of 11%), as well as patient information and education (absolute increase of 13%).²⁴

4.7.4 Site Allocation

The study statistician will randomly allocate the health systems to the order in which they will receive the intervention. No criteria are set on the randomization as there is only three systems participating.

5.0 Potential Limitation

5.1 Conflict of Interest

Tools under evaluation are not part of any existing effort to commercialize or profit from their use; the researchers involved in this study have not received -- and will not receive with their application in this study -- any royalties or other monetary benefits, directly or indirectly, from the use of the decision aids.

6.0 Human Subjects

Participation will be completely voluntary and we have procedures in place, sanctioned by the Mayo Clinic Institutional Review Board, to ensure that participants have the opportunity to opt out at any time. Study launch, recruitment, participant consent, and data collection will be performed by study personnel with human subjects training and approvals. This will be a multi-site study conducted at three health systems. Mayo Clinic will serve as the coordinating center. Reliance agreements will be in place with all study settings before the conduct of any human subjects research.

Each healthcare system will identify eligible patients whom do not have restrictions on use of their electronic health record for research purposes. The system will then create a random ID for each patient that they hold the key to, adding security to the data transfer of the EHR data in that the potential PHI transferred is the date of the clinical appointment and the clinical note. The health system has the option of running the clinical note through a de-identification algorithm for a free text field if they or their IRB feel it is necessary. The receipt of the data will be conducted through a HIPAA compliant system of which once the data is stored will be accessible to the study statistician and key study personnel that have the appropriate training and credentials as needed.

For patients whose electronic health record data is eligible to be abstracted, we will follow any local policies for data authorization. An example is the Minnesota Research Authorization, which is a Minnesota law that requires that Mayo Clinic ask patients seen at its campus in Rochester, Minn., or affiliated Minnesota entities, for permission before using their medical records for research, a process called research authorization.

6.1 Population

This study will be available to all eligible patients, regardless of race, gender, or ethnic origin. There is no information currently available regarding differential outcomes of the decision aid in subsets defined by race, gender, or ethnicity, and there is no reason to expect such differences to exist. Therefore, although the planned analysis will, as always, look for differences in treatment effect based on racial and gender groupings, the sample size is not increased in order to provide additional power for subset analyses.

6.2 Potential Risks

Potential risks to patient subjects should be minimal. Given that the intervention has been extensively pilot tested and no adverse outcomes occurred, we do not expect early termination due to harm. The intervention is an educational tool for use during the clinic visit to help patients make decisions about diabetes medications. The tool does not make recommendations or result in prescriptions without the participation of the clinician, and the tool is not to be used outside a clinical visit in which a clinician can place the information in context. The rest of the intervention is to help practices adopt best practices. The only potential risk could be loss of privacy through the data collected. The forms and surveys will not contain names, but instead contain anonymous ID's. The patient encounter data will also be de-identified prior to transfer to study team. All electronic files will be stored on password-protected servers in which only authorized personnel have access. Audio/video files will be uploaded to the Mayo Clinic server immediately following the recording of a clinical encounter. In situations where access to the server is limited, USB's/external hard drives that are secure and password-protected will be used to temporarily store audio/video files until connection to the Mayo Clinic server is restored. These USB's/external hard drives are encrypted and will be used in accordance with Mayo Clinic's Portable Computing and Telecommunication Devices Policy.

6.3 Protection and Confidentiality

6.3.1 Subject privacy

In this study, the privacy of all study participants will be protected by avoiding the use of names on all research data (including field notes, transcribed conference call, meeting tapes, audio-and video-recordings of the interviews, transcripts). All study participants will be identified by a unique study code number only. The link between the code number and study participant's identity for the subject (patient) data will be stored within each health systems server, where only staff identified within the health system that can have access to that knowledge will. A spreadsheet of clinician and other key personnel name with a link to their study ID will be stored on a secure server behind Mayo's firewall. This spreadsheet will be deleted after all participant follow-up has been completed. Names of those who decline participation in the study will be maintained in a do-not-call list, so they will not be contacted multiple times (as patients are likely to have multiple appointments at participating clinics during the study). All research material will be maintained on a secure server at the KER Unit at Mayo Clinic and locked in file cabinets, and all material will be destroyed seven years following completion of the study.

6.3.2 Data management:

All sites will be required to use the current version of all documents and forms and adhere to the study schedule. Forms and documents will be returned to study coordinators via fax, e-mail, or intra-clinic courier. Data from surveys will be captured via Qualtrics, and additional data via paper completed surveys or tracking of completion will be completed via data entry specialists into a HIPAA compliant secure data entry system that allows for validated data entry, edit checks and logs of all data changes. Within both systems the data can be accessed by the statistical team at any time and downloaded into a statistical software package. The statistical team will review the data on a monthly basis to ensure data accuracy and completeness. All data, documents, and analysis findings will be housed within the Mayo Clinic system that is password protected and backed up on a nightly basis. The data will be stored within the secure system for seven years following completion of the study.

6.3.3 Video and audio-recordings

Semi-structured interviews will be audio recorded with permission of all participants. Some health visits will be video recorded with permission of all participants. These recordings are conducted using a portable digital video camera that is placed aimed at the clinician's desk, away from the physical examination table. The clinician and the patient will be instructed on how to occlude the lens, direct the camera to a wall, or turn off the camera at any time they feel this is appropriate. Digital recordings are immediately uploaded to the research team's secure server and deleted from portable devices after overnight back-up of Mayo's servers. The video and audio files are identified using a code number that does not include the name of the clinician, support staff, or patient or reference to their medical record number or date of birth. All transcriptions omit names that may have been stating during the recording, which are replaced in the transcript by purposefully false initials. The research data are only accessible with password protected and logged access at Mayo Clinic; all of these personnel have received human subjects

research training. The video and audio files will be kept for seven years following completion of the study and then deleted from the server.

6.3.4 Data and Safety Monitoring Plan

This study will employ a Data Safety and Monitoring Plan (DSMP), as included in the application. The study does not plan to employ a Data Safety Monitoring Board (DSMB). The decision not to establish a DSMB was based on the fact that (1) this is not a Phase III clinical trial; (2) the study will not employ a high-risk intervention; (3) the study is not blinded (masked); and (4) the study does not involve vulnerable populations. Despite this assessment, we will work with NHLBI, upon award, to develop a data safety monitoring process that is acceptable, including establishment of a DSMB as needed.

7.0 References

1. Murphy SL, Xu J, Kochanek KD, Arias E. Mortality in the United States, 2017. In. NCHS Data Brief, no 328 ed. Hyattsville, MD: National Center for Health Statistics; 2018.
2. Go AS, Mozaffarian D, Roger VL, et al. Heart disease and stroke statistics--2013 update: a report from the American Heart Association. *Circulation*. 2013;127(1):e6-e245.
3. Mahmood SS, Levy D, Vasan RS, Wang TJ. The Framingham Heart Study and the epidemiology of cardiovascular disease: a historical perspective. *Lancet (London, England)*. 2014;383(9921):999-1008.
4. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease. *Journal of the American College of Cardiology*. 2019.
5. Ko DT, Mamdani M, Alter DA. Lipid-lowering therapy with statins in high-risk elderly patients: the treatment-risk paradox. *Jama*. 2004;291(15):1864-1870.
6. McAlister FA, Oreopoulos A, Norris CM, et al. Exploring the Treatment-Risk Paradox in Coronary Disease. *Archives of internal medicine*. 2007;167(10):1019-1025.
7. McCoy RG, Dykhoff HJ, Sangaralingham L, et al. Adoption of New Glucose-Lowering Medications in the U.S.-The Case of SGLT2 Inhibitors: Nationwide Cohort Study. *Diabetes technology & therapeutics*. 2019;21(12):702-712.
8. Nieuwlaat R, Schwalm J-D, Khatib R, Yusuf S. Why are we failing to implement effective therapies in cardiovascular disease? *European Heart Journal*. 2013;34(17):1262-1269.
9. Weymiller AJ, Montori VM, Jones LA, et al. Helping patients with type 2 diabetes mellitus make treatment decisions: statin choice randomized trial. *Archives of internal medicine*. 2007;167(10):1076-1082.
10. Leppin A, Boehmer KR, Branda ME, et al. Developing a toolkit to implement the Statin Choice Conversation Aid at scale: application of a work reduction model. *BMC Health Services Research*. 2019;19(1):249.
11. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50.
12. May C, Finch T, Mair F, et al. Understanding the implementation of complex interventions in health care: the normalization process model. *BMC Health Services Research*. 2007;7(1):148.
13. Murray E, Treweek S, Pope C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC medicine*. 2010;8:63-63.
14. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American journal of public health*. 1999;89(9):1322-1327.

15. Forcino RC, Yen RW, Aboumrad M, et al. US-based cross-sectional survey of clinicians' knowledge and attitudes about shared decision-making across healthcare professions and specialties. *BMJ Open*. 2018;8(10):e022730.
16. Finch TL, Girling M, May CR, et al. Improving the normalization of complex interventions: part 2 - validation of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). *BMC Medical Research Methodology*. 2018;18(1):135.
17. Finch TL, Rapley T, Girling M, et al. Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol. *Implementation Science*. 2013;8(1):43.
18. Rapley T, Girling M, Mair FS, et al. Improving the normalization of complex interventions: part 1 - development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). *BMC Medical Research Methodology*. 2018;18(1):133.
19. Moullin, J.C., Sklar, M., Ehrhart, M.G. et al. Provider REport of Sustainment Scale (PRESS): development and validation of a brief measure of inner context sustainment. *Implementation Sci* 16, 86 (2021). <https://doi.org/10.1186/s13012-021-01152-w>
20. Mercer SW, Maxwell M, Heaney D, Watt GC. The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure. *Family Practice*. 2004;21(6):699-705.
21. Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Educ Couns*. 2010;80(1):94-99.
22. Wyatt KD, Branda ME, Anderson RT, et al. Peering into the black box: a meta-analysis of how clinicians use decision aids during clinical encounters. *Implementation Science*. 2014;9(1):26.
23. Hayes RJ, Moulton LH. *Cluster randomised trials*. 2nd Edition ed. Boca Raton, FL: CRC Press; 2017.
24. Schedlbauer A, Davies P, Fahey T. Interventions to improve adherence to lipid lowering medication. *The Cochrane database of systematic reviews*. 2010(3):Cd004371.